



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/594,486	09/27/2006	Esa Jarvi	1764 WO/US	1337												
7590 Christine M Rebman Mallinckrodt Inc 675 McDonnell Boulevard PO Box 5840 St Louis, MI 63134		02/08/2008	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">SOLOLA, TAOFIQ A</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1625</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>02/08/2008</td><td>PAPER</td></tr></table>		EXAMINER		SOLOLA, TAOFIQ A		ART UNIT	PAPER NUMBER	1625		MAIL DATE	DELIVERY MODE	02/08/2008	PAPER
EXAMINER																
SOLOLA, TAOFIQ A																
ART UNIT	PAPER NUMBER															
1625																
MAIL DATE	DELIVERY MODE															
02/08/2008	PAPER															

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/594,486	JARVI ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: ____ |

Claims 1-20 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phraseology "contains less than about 1.0/0.1 wt. % during hydrogenation," is not clear and therefore the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossey et al., US 4,794,185, in view of, March, Adv. Org. Chem. 2nd Ed. (1977), p. 402.

Applicant claims a process of making compounds of formula 1A from compounds of formula 1, comprising hydrogenolysis of the alcohol in compound 1A with at a strong acid, halide, catalyst, and an hydrogen source, wherein formula 1:water is 2:1. In preferred embodiments, the catalyst is palladium on carbon, the reaction mixture comprises water scavenger: acetic anhydride (generated in situ from acetic acid) and carboxylic acid anhydride; the acid is sulfuric acid, and the halide is bromide. Applicant also claims various percents weight of water.

Determination of the scope and content of the prior art (MPEP 2141.01)

Rossey et al., teach a similar process comprising NaBH_4 as catalyst, SOCl_2 , 1, 2-dichloromethane, water and sodium carbonate. See col. 3, line 60 to col. 4, line 20.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Rossey et al., is that applicant use palladium catalyst, hydrogen source, water scavenger and the reaction is one pot instead of two-pot by Rossey et al.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, March teach hydrogenolysis of alcohols in a one pot process using hydrogen source and palladium on carbon as catalyst. See Rxn. 0-79, pp. 402. It is well known that SOCl_2 reacts with water to produce SO_2 and HCl ($\text{SOCl}_2 + \text{H}_2\text{O} = 2\text{HCl} + \text{SO}_2$). Therefore, in the process of Rossey et al., SOCl_2 is a water scavenger as well as a source of acid. Chloride and bromide are well known halogens and have been used interchangeably for centuries.

Applicant's process is a selective combination of the teachings of the prior arts done in a manner obvious to one of ordinary skill in the art. There is no indication that such modification would lead one of ordinary skill in the art to doubt that the modification could not be made. *In re Mostovych*, 144 USPQ 38 (CCPA, 1964). Changing the ratio or percent weight of water is an obvious modification available to the preference of an artisan. It is a mere optimization of a variable, which is not patentable absent unexpected result due to each variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller*, 22 F.2d 454, 105 USPQ 233 (CCPA, 1955).

Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art would have known to use any strong acid instead of HCl , use any water scavenger and optimize the variables at the time this invention was made. The

motivation is to maximize the yield of the product, and because the modifications are within routine effort of an artisan.

Alternatively, given the teachings of the prior arts it would have been obvious to try and make the modifications at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done separately. *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

Alternatively, given the teachings of the prior arts one would have known to make the modifications of the teachings of the prior arts at the time the invention was made. "When a

work is available in one field of endeavour, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technology is obvious unless its actual application is beyond his or her skill." "One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ----, 82 USPQ2d 1385 (2007).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER

Group 1625

February 1, 2008